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08/783,734	01/16/1997	JEFFREY M. FRIEDMAN	600-1-162CP2	1933
7590 01/15/2004 KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			EXAMINER O HARA, EILEEN B	
			ART UNIT	PAPER NUMBER

1646

DATE MAILED: 01/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

08/783,734

Applicant(s)

FRIEDMAN ET AL.

Examiner

Eileen O'Hara

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 29-33 and 67-73 is/are pending in the application.
- 4a) Of the above claim(s) 32,33 and 67-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 29-33 and 67-73 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11/24/00. 6) ☐ Other: \_\_\_\_

### **DETAILED ACTION**

1. Claims 29-33 and 67-73 are pending in the instant application.

#### ***Election/Restrictions***

2. Applicant's election with traverse of Group I, drawn to murine splice variant OB-Re oligonucleotides, and oligonucleotides hybridizable to the nucleic acid molecule which codes on expression a polypeptide of a leptin receptor OB-Re (SEQ ID NO: 10) in the Paper filed Oct. 20, 2003, is acknowledged. The traversal is on the ground(s) that even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.2): 1) separate classification, 2) separate status in the art; or 3) different field of search. Applicants additionally point out that under Patent Office examining procedures, "If the search and examination of an entire application can be made without serious burden, the Examiner is encouraged to examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803< Rev. 8, May 1988). Applicants also submit that Claims 29-33 of Group I are drawn o oligonucleotides hybridizing to a nucleic acid encoding a specific receptor species that are fundamentally related to Claims 67-73 of Group II, drawn to methods for diagnosing body weight abnormalities comprising detecting said OB-receptor species using these oligonucleotides, and the search for any of the methods separately classified by the Examiner as the invention of Group II would require an additional search of the identical classes wherein the oligonucleotides of Group I are classified, thus resulting in a duplicate search for the same material, and therefore Applicants submit that the Search and Examination of the entire Application, or at least, of Group I with Group II can be made without serious burden.

Art Unit: 1646

This is not found persuasive because under MPEP § 803, there are two criteria for a proper requirement for restriction between patentably distinct inventions:

(A) The inventions must be independent (see MPEP § 8702.01, 806.04, 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(I): and

(B) There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a) - § 806.04(I), § 808.01(a), and § 808.02).

Consistent with current patent practice, a serious search burden may be established by (A) separate classification thereof: (B) a separate status in the art when they are classifiable together: (C) a different field of search:. The splice variants of the different groups would require separate sequence searches, which would be a different field of search for each group. Thus, the groups require divergent searches, and to search all inventions would be burdensome.

The requirement is still deemed proper and is therefore made FINAL. However, Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

**Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or notice of allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Art Unit: 1646

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claims 32, 33 and 67-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 20.

Claims 29-31 are currently under examination and will be examined as far as they relate to the OB-Re splice variant of SEQ ID NO: 10.

***Priority***

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. and 120 as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

***Advisory Information***

4. Claims 29-31 are being examined as they are drawn only to oligonucleotides hybridizable to a DNA molecule of SEQ ID NO: 9 (claim 30, section a and section c. i, 8, ii (5) and section e) or hybridizable to a nucleic acid which codes on expression for a polypeptide of SEQ ID NO: 10.

***Claim Objections***

5.1 Claims 29-31 are objected to because of the following informalities: they encompass non-elected inventions, which should be deleted. Appropriate correction is required.

5.2 Claim 30 is objected to because it is not in sequence compliance. The elected invention of claim 30 encompasses oligonucleotides hybridizable to a leptin (OB-Re) polypeptide wherein the N-terminal sequence is amino acid residues 28-796 (SEQ ID NO: 116) and the C-terminal sequence is NO: 15 after His 796 (SEQ ID NO: 120), wherein the numbering is based on the amino acid sequence of SEQ ID NO: 84. Claim 30 does not comply with 37 CFR j 1.822(e) which states that (a) sequence that is made up of one or more noncontiguous segments of a larger sequence or segments from different sequences shall be presented as a separate sequence".

However, the elected hybrid leptin polypeptide is identical to the polypeptide of SEQ ID NO: 10,

Art Unit: 1646

with the exception that it is lacking the first 27 amino acids of SEQ ID NO: 10. For clarity, it is recommended that the claim be amended to claim the oligonucleotide as follows: "leptin receptor polypeptide consisting of amino acids 28-805 of SEQ ID NO: 10". Otherwise, a new CRF and sequence listing will be required that recite the elected hybrid by a separate SEQ ID NO:, and the claims and the instant specification would also need to be amended so that they comply with 37 C.F.R. j 1.821(d) which requires a reference to that particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. For rules interpretation Applicant may call (703) 308-1123. See M.P.E.P. 2422.04.

If applicants elect to claim the hybrid receptor this way, the specification would also need to be amended so that it identifies the hybrid in the same way. This would not constitute new matter.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 29-31 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21, 22, 24, 26-28, 34-48,

Art Unit: 1646

51, 52 and 67 of copending Application No. 08599974. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to nucleic acid molecules of SEQ ID NO: 9 or encoding the protein of SEQ ID NO: 10.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 29-31 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 29-31, as written, do not sufficiently distinguish over nucleic acids of SEQ ID NO: 9 or encoding the protein of SEQ ID NO: 10 (leptin receptors) as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of “isolated” or “purified”. See MPEP 2105.



***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 29-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification describes a polypeptide sequence consisting of SEQ ID NO: 84, which is the murine full-length leptin (OB) receptor, and a splice variant (SEQ ID NO: 10) that is a soluble form of the full-length receptor. The claims are directed to oligonucleotides that a hybridizable to the splice variant, the protein of which is shown to have the following activity: binding leptin. However, the claims as written include oligonucleotides comprising fragments and homologues, encompass oligonucleotides that vary substantially in length and also in nucleic acid composition. The instant disclosure of a full-length protein, that of SEQ ID NO: 84, and the splice variants, all of which are identical to at least amino acids 1-664 of SEQ ID NO: 84, which is the majority of the extracellular domain, does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera. A genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v Eli Lilly & Co*, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

“To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the inventor invented the claimed invention”. Lockwood v. American Airlines, Inc., 107 F.3d 1565,

Art Unit: 1646

1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1980) (“[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.”) Thus, an applicant complies with the written description requirement “by describing the invention, with all its claimed limitations, not that which makes it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” Lockwood, 107 F.3d 1565, 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the ‘525 patent, “requires a precise definition, such as by structure, formula, chemical name, or physical properties,” not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, “an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself.” Id at 1170, 25 USPQ2d at 1606.”

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. The instant specification discloses, however, nucleic acids encoding the polypeptide sequence SEQ ID NO: 84 and five splice variants. Given the unpredictability of homology comparisons, and the fact that the specification fails to provide objective evidence that the additional sequences are indeed species of the claimed genus it cannot be established that a representative number of species have been disclosed to support the genus claim. The instantly claimed genus is not so limited and the prior art does not provide compensatory structural or correlative teachings to enable one of skill to identify the oligonucleotides encompassed.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 29-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29-31 are indefinite because they encompass an oligonucleotide molecule hybridizable under “stringent” conditions. Though the specification on pages 37-38 describes various hybridization and wash conditions, they are exemplary. The term “stringent conditions” is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 29-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Tartaglia et al., US Patent No. 6,506,877, filing date Dec. 28, 1995.

Art Unit: 1646

Claims 29-31 encompass oligonucleotides that are hybridizable to a DNA molecule of SEQ ID NO: 9 or hybridizable to a nucleic acid which codes on expression for a polypeptide of SEQ ID NO: 10 or to the complements of the forgoing.

Tartaglia et al. disclose murine Ob (leptin) receptor (SEQ ID NO: 2) that is 100% identical to amino acids 1-796 of SEQ ID NO: 10 of the instant invention, and nucleic acid (SEQ ID NO: 1) which is 98.9% identical to nucleotides 1-2443 of SEQ ID NO: 9 of the instant invention. Those nucleotides are 99.4% of the entire open reading frame (the open reading frame of SEQ ID NO: 9 is nucleotides 44-2457). The nucleic acid of Tartaglia et al. would be hybridizable to a DNA molecule of SEQ ID NO: 9, and therefore Tartaglia et al. anticipates the claims.

### ***Conclusion***

11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM. ***Applicant is advised that effective January 23, 2003, the Examiner's phone number will be (571) 272-0878.***

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564. ***Applicant is advised that effective January 23, 2003, Yvonne Eyler's phone number will be (571) 272-0871.***

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.


Art Unit: 1646

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

A handwritten signature in cursive script that reads "Eileen B. O'Hara". The signature is written in black ink and is positioned below the printed name.

Patent Examiner